

**UNITED STATES PATENT APPLICATION
OF
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FOR
LEFT VENTRICULAR CONDUITS AND METHODS FOR DELIVERY**

Cross Reference to Related Applications

This application claims the benefits of U.S. Provisional Application No. 60/147,211, filed August 4, 1999.

Field of the Invention

The present invention relates to an apparatus for bypassing a blocked or stenosed blood vessel segment, and, more particularly, to an apparatus and method for delivering a conduit between the coronary artery and the left ventricle of the heart.

Background of the Invention

Coronary artery disease is a major problem in the U.S. and throughout the world. Coronary arteries as well as other blood vessels frequently become clogged with plaque which, at the very least, can reduce blood and oxygen flow to the heart muscle (myocardium), and may impair the efficiency of the heart's pumping action, and can lead to heart attack (myocardial infarction) and death. In some cases, these coronary arteries can be unblocked through non-invasive techniques such as balloon angioplasty. In more difficult cases, a surgical bypass of the blocked vessel is necessary.

In a coronary bypass operation, one or more venous segments are inserted between the aorta and the coronary artery, or, alternatively, the distal end of an internal mammary artery is anastomosed to the coronary artery at a site distal to the stenosis or occlusion. The inserted venous segments or transplants act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than

500,000 bypass procedures are performed in the U.S. every year.

Such coronary artery bypass graft (CABG) surgery, however, is a very intrusive procedure which is expensive, time-consuming, and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and that the patient be placed on a heart-lung bypass pump so that the heart can be operated on while not beating. A saphenous vein graft is harvested from the patient's leg, another highly invasive procedure, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence are prolonged. Furthermore, many patients are poor surgical candidates due to other concomitant illnesses.

As mentioned above, another conventional treatment is percutaneous transluminal coronary angioplasty (PTCA) or other types of angioplasty. However, such vascular treatments are not always indicated due to the type or location of the blockage or stenosis, or due to the risk of emboli.

Thus, there is a need for an improved coronary bypass system which is less traumatic to the patient.

Summary of the Invention

Briefly stated, the methods and apparatus described and illustrated herein generally relate to direct coronary revascularization, wherein a conduit or opening is provided from the left ventricle to the coronary artery, oftentimes the left anterior descending (LAD), to provide blood flow directly therethrough. These methods and apparatus are particularly useful when a blockage partially

or completely obstructs the coronary artery, in which case the bypass conduit or opening is positioned distal to the blockage. More preferably, conduits are provided to direct blood flow from the left ventricle to a coronary artery at a location distal to a blockage in the coronary artery. The conduits may be threaded to facilitate insertion into a patient's heart wall and to control the depth of insertion. Threaded and nonthreaded conduits are preferably delivered using a guidewire approach. In this approach, the guidewire is placed through a needle that is inserted into the left ventricle. After the guidewire is placed, the needle is removed. In one embodiment, a dilator is provided over the guidewire into the heart wall, and the conduit is delivered over the dilator. In another embodiment, an introducer sleeve is provided over the dilator into the heart wall, the dilator is removed, and the conduit is delivered through the introducer sleeve. A depth measuring tool is preferably used to determine the appropriate length of the conduit prior to delivery. In another embodiment, a feature can be included on the end of the introducer sleeve that engages with the arterial wall, and when pulled back, distends the artery. The conduit can then be advanced until the deployable flanges seat against the bottom of the artery.

Brief Description of the Drawings

FIGURE 1 is a schematic side view of a threaded conduit inserted into a heart wall of a patient between the left ventricle and a coronary artery according to a preferred embodiment of the present invention.

FIGURE 2 is a side view of a heart having a needle inserted through a coronary artery to the left ventricle, and a guidewire inserted therethrough.

FIGURE 2A is a side view showing a needle being inserted through a coronary artery into the left ventricle.

FIGURE 2B is a side view of a guidewire inserted through the needle of **FIGURE 2A**, with the needle being removed.

FIGURE 3 is a side view of a dilator being inserted over the guidewire of **FIGURE 2**.

FIGURE 3A is a side view of an introducer being advanced over the guidewire of **FIGURE 2B**.

FIGURE 4 is a side view of a threaded conduit being inserted over the dilator of **FIGURE 3**.

FIGURE 4A is a side view of a tool being used to insert a threaded conduit inserted over the dilator of **FIGURE 3A**.

FIGURE 5 is a side view showing the threaded conduit of **FIGURE 4** being advanced into position.

FIGURES 5A-5D are the side views of **FIGURES 2A, 2B, 3A and 4A**, more particularly showing features included on the needle, introducer and deployment tool that aid in determining the proper deployment depth.

FIGURE 6 is a side view of a sleeve being placed for shunt insertion.

FIGURE 7A is a side view of a conduit being inserted through the sleeve of **FIGURE 6** using a stylet.

FIGURE 7B illustrates the conduit of **FIGURE 7A** having flanges.

FIGURE 8 is a side view of the stylet and sleeve of **FIGURE 7A** being

removed.

FIGURES 8A-8C are side views of a delivery system for a nonthreaded conduit illustrating a bulb feature on the outer introducer sleeve that aids in holding the artery open and achieving proper placement of the device.

FIGURE 9 is a schematic side view of a two piece threaded stylet and sleeve.

FIGURE 10 is a schematic side view of a depth measuring tool.

FIGURE 11 is a cross-sectional view of an introducer sleeve having a side lumen for depth measurement.

FIGURES 12A-12D are schematic side views of the delivery of a conduit from the coronary artery to the left ventricle using a dilator and introducer.

FIGURES 13A-13B are schematic side views of threads used to hold open the coronary artery.

FIGURE 14 is a table of the pull out forces of various threaded conduits that may be used according to certain embodiments of the present invention.

FIGURE 15 is a table of pull out forces of various barbed conduits that may be used according to certain embodiments of the present invention.

FIGURE 16 is a table of push-through forces of various conduits having flanges that may be used according to certain embodiments of the present invention.

Detailed Description of the Preferred Embodiment

As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. Oxygenated blood that has returned from the lungs to the heart then flows from the heart to the aorta. Some blood in the aorta flows into the coronary arteries, and the remainder of blood in the aorta flows on to the rest of the body. The coronary arteries are the primary blood supply to the heart muscle and are thus critical to life. In some individuals, atherosclerotic plaque, aggregated platelets, and/or thrombi build up within the coronary artery, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death. The presence of coronary vasospasm, also known as "variant angina" or "Prinzmetal's angina," compounds this problem in many patients.

The principles of the present invention are not limited to left ventricular conduits, and include conduits for communicating bodily fluids from any space within a patient to another space within a patient, including any mammal. Furthermore, such fluid communication through the conduits is not limited to any particular direction of flow and can be antegrade or retrograde with respect to the normal flow of fluid. Moreover, the conduits may communicate between a bodily space and a vessel or from one vessel to another vessel (such as an artery to a vein or vice versa). Moreover, the conduits can reside in a single bodily space so as to communicate fluids from one portion of the space to another. For example, the conduits can be used to achieve a bypass within a single vessel, such as communicating blood from a proximal portion of an occluded coronary artery to a more distal portion of that same coronary artery.

In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit communicates from the left ventricle, through the myocardium, into the pericardial space, and then into the coronary artery. However, other preferred embodiments are disclosed, including direct transmyocardial communication from a left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other non-myocardial and even non-cardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, septum, etc.

The bypass which is achieved with certain preferred embodiments and related methods is not limited to a complete bypass of bodily fluid flow, but can also include a partial bypass which advantageously supplements the normal bodily blood flow. Moreover, the occlusions which are bypassed may be of a partial or complete nature, and therefore the terminology "bypass" or "occlusion" should not be construed to be limited to a complete bypass or a complete occlusion but can include partial bypass and partial occlusion as described.

The preferred conduits and related methods disclosed herein can also provide complete passages or partial passages through bodily tissues. In this

regard, the conduits can comprise stents, shunts, or the like, and therefore provide a passageway or opening for bodily fluid such as blood. Moreover, the conduits are not necessarily stented or lined with a device but can comprise mere tunnels or openings formed in the tissues of the patient.

The conduits of the present invention preferably comprise both integral or one-piece conduits as well as plural sections joined together to form a continuous conduit. The present conduits can be deployed in a variety of methods consistent with sound medical practice including vascular or surgical deliveries, including minimally invasive techniques. For example, various preferred embodiments of delivery rods and associated methods may be used. In one embodiment, the delivery rod is solid and trocar-like. It may be rigid or semi-rigid and capable of penetrating the tissues of the patient and thereby form the conduit, in whole or in part, for purposes of fluid communication. In other preferred embodiments, the delivery rods may be hollow so as to form the conduits themselves (e.g., the conduits are preferably self-implanting or self-inserting) or have a conduit mounted thereon (e.g., the delivery rod is preferably withdrawn leaving the conduit installed). Thus, the preferred conduit device and method for installation is preferably determined by appropriate patient indications in accordance with sound medical practices.

FIGURE 1 illustrates schematically a threaded conduit according to one preferred embodiment of the present invention. The conduit 10 is preferably an elongate tubular body having a proximal end 12 and a distal end 14 and a lumen (not shown) extending therethrough. The proximal end 12 preferably tapers to

the desired internal diameter (ID) of the device. The majority of the conduit 10 is threaded with threads 16 to facilitate insertion of the conduit into the heart, as described below. In one preferred embodiment, the entire body of the conduit 10 is threaded except for the proximal tip 12 of the conduit. The conduit may or may not have flange-like features 13 on its distal end that engage with the artery lumen. In addition, the conduit may or may not have a ring 15 for engaging the artery and allowing blood to pass therethrough. **FIGURE 1** illustrates the conduit 10 as implanted in a patient, wherein the conduit preferably extends between the left ventricle LV, through the myocardium MYO and into the coronary artery CA.

FIGURES 2-5 illustrate one embodiment for delivering the conduit 10 into a patient. Although these figures illustrate a pig heart, it will be appreciated that the methods described herein apply to human hearts as well. To deliver the conduit 10 into the myocardium of the heart PH, a needle 18, as shown in **FIGURE 2**, is first inserted through the heart wall into the left ventricle (also illustrated in **FIGURE 2A**). The needle 18 is preferably hollow, and is preferably inserted through an anterior wall and then a posterior wall of the coronary artery CA. After the needle is inserted, access to the left ventricle may be verified. If it is necessary to relocate the needle, the needle leaves only a very small hole upon removal.

As shown in **FIGURE 2**, after the needle is placed in the left ventricle, a guidewire 20 is inserted into the lumen in the needle. The guidewire is preferably a 0.014 guidewire, which extends into the left ventricle through the

needle. After placement of the guidewire the needle is removed, as illustrated in **FIGURE 2B.**

As shown in **FIGURES 3 and 3A**, a dilator or introducer 22 is preferably inserted over the guidewire and into the heart until the dilator reaches the left ventricle. Upon reaching this position, the guidewire 20 is removed from the heart.

As shown in **FIGURES 4 and 4A**, a threaded conduit 10, such as described with respect to **FIGURE 1** above, is placed over the dilator. The non-threaded tapered tip 16 (shown in **FIGURE 1**) of the conduit is inserted into the coronary artery. The conduit 10 is then preferably pulled back to open the artery. The first few threads are then advanced by twisting the threaded conduit. The conduit 10 may be in the form of a shunt.

A tool 24 is then used to advance the conduit 10 to the proper depth, as shown in **FIGURES 5 and 4A**. More preferably, the tool 24 mates with the distal end of the conduit in order to turn the conduit. Because the conduit 10 is threaded, the tool 24 can easily adjust the conduit to a desired depth. After the conduit 10 reaches the desired depth, the tool and the dilator are removed, leaving the conduit 10 in place.

In **FIGURES 5A-5D**, features are shown on the components of the delivery system illustrated in **FIGURES 2A, 2B, 3A and 4A** to help determine the proper depth to insert the device. As shown in **FIGURE 5A**, depth markers 19 on the needle 18 can be used to determine the thickness of the myocardium,

and ensure that the device used will reach the left ventricle. As shown in **FIGURES 5C and 5D**, a bleed hole 23 in the dilator/introducer 22 can be used to determine the location of the lumen of the artery, and a depth marker 25 on the dilator/introducer, coupled with a window 27 in the deployment tool 24, can be used to determine when the threaded device 10 has been inserted to the proper depth.

FIGURES 6-8 illustrate another embodiment for delivering a conduit into a patient's heart, where the conduit need not be threaded. As described and shown with respect to **FIGURES 2 and 3** above, a dilator is preferably placed into the heart through the coronary artery using a needle and a guidewire. As shown in **FIGURE 6**, a sleeve 26 is placed over the dilator and inserted into the patient's heart. The dilator is then removed.

As shown in **FIGURE 7A**, a conduit 10 is inserted into the sleeve 26. The conduit may be in the form of a shunt, as illustrated in **FIGURE 7A**. The conduit, as shown in **FIGURE 7B**, may have flanges 28 on its distal end 14 which will assist in anchoring the conduit 10 to the artery. The conduit 10 is placed in the sleeve 26 by collapsing the flanges 28 into the sleeve. The conduit is advanced using a stepped stylet 30, as shown in **FIGURE 8**, to the proper depth. This depth may be determined using an external depth measuring gauge. Holding the stylet 30 stationary, the sleeve is removed, releasing the flanges 28, preferably in the artery CA. Then the stylet is removed, leaving the conduit 10 in place.

In FIGURES 8A-8C, another embodiment for inserting a non-threaded conduit is shown, wherein a bulbous feature is included on a sleeve for holding the artery open.

In this embodiment, the dilator 22, conduit 10, and sleeve 26 are assembled as shown, and inserted through the coronary artery and into the myocardium until the bulbous feature 29 is inside the lumen of the artery. The assembly is then pulled back, so that the bulbous feature 29 distends the artery. The stepped dilator 22 is then pushed into the left ventricle, advancing the conduit 10 while the sleeve 26 is held in place. The flanges 28 then deploy outside the sleeve, but inside the artery. The conduit can be advanced until the flanges bottom out on the bottom wall of the artery, then the sleeve 26 and dilator 22 can be removed. Several configurations of bulbous features can be incorporated, including a short threaded section, a balloon, or any deployable features that extend past the outer diameter (OD) of the sleeve thereby anchoring the sleeve in the lumen of the artery. It is also understood that the dilator, conduit, and sleeve can be inserted as an assembly, or individually in which case the conduit is backloaded into the sleeve after the sleeve has been placed.

It will be appreciated that various conduit configurations can be used in accordance with the embodiments of the present invention. For instance, threaded conduits, conduits with barbs and conduits with flanges may all be used. FIGURE 14 shows a table of the pull out forces of various threaded conduits that may be used. FIGURE 15 shows a table of the pull out forces of

various barbed conduits that may be used. **FIGURE 16** shows a table of the push-through forces of various conduits having flanges that may be used.

FIGURE 9 illustrates a two piece threaded stylet and sleeve for delivery of a conduit. The stylet 54 is preferably threaded only on its distal tip 56 which is to be inserted into the myocardium MYO to the left ventricle. The sleeve 58 is preferably threaded over its entire body. The stylet 54 and the sleeve 58 are preferably threaded simultaneously into the myocardium. The stylet is then removed, and a conduit (not shown) for providing blood flow between the left ventricle and coronary artery is inserted through the sleeve while the threads on the sleeve hold the artery open. After insertion of the conduit the sleeve is removed. Alternatively, the threaded sleeve can function as the conduit itself.

In another embodiment, not shown, a method is provided for insertion of a curved conduit. This embodiment is useful where it is desired to provide a curved conduit between the left ventricle and coronary artery. A curved stylet is preferably inserted into the heart wall from the coronary artery to the left ventricle. A nonthreaded conduit is advanced over the curved stylet using a threaded flexible tool placed over the conduit. The threaded flexible tool is preferably attached to the conduit in order to advance the conduit over the stylet. The conduit is inserted by turning the tool until the conduit is in its desired location. In this embodiment, the conduit can be rigid or flexible.

FIGURE 10 illustrates a depth measuring tool 72 for measuring the depth of the coronary artery and/or myocardium. In one embodiment, the tool 72 has a

proximal end 74 with an access port 78 in fluid communication with an opening 80 on the distal end 76. Also on the distal end are markers 82 used to measure the depth of insertion of the access port 78. The proximal end is preferably tapered, and is inserted into the myocardium to the left ventricle. When the access port reaches the left ventricle, blood flows through the port and out the opening. At this point the depth of the myocardium can be determined with the markers 82. A bypass conduit 84 can then be inserted over the tool, the conduit having a length determined based on the depth d of the myocardium measured by the tool 72.

In another embodiment shown in **FIGURE 11**, a depth measuring tool may be implemented within an introducer sleeve 26 such as described above. In this embodiment, the sleeve 26 has a main lumen 32 for introduction of the conduit as described above, and also has a secondary lumen 34 in fluid communication with an access port 36 for measuring the depth of insertion of the introducer sleeve. For instance, when the sleeve 26 is inserted through the heart wall toward the left ventricle, when the sleeve reaches the left ventricle blood flows through the access port and out an opening 38 on the opposite end. Once this location is reached, markers provided on the outside of the sleeve, as described with respect to **FIGURE 10**, are used to determine the desired size of the conduit to be inserted through the lumen 32. It will be appreciated that the depth measuring tools described above may be calibrated so that the access port is located in the coronary artery to indicate positioning therein.

FIGURES 12A-12D illustrate the delivery of a conduit 86 using a dilator

and an introducer according to another embodiment of the present invention. As shown in **FIGURE 12A**, a template 88 is placed on the outside of the heart for positioning and a needle 90 is inserted therethrough into the coronary artery, through the myocardium and into the left ventricle. The needle 90 is hollow, and a guidewire 92 is inserted through the needle to the left ventricle, as shown in **FIGURE 12B**. A dilator 94 is loaded onto the guidewire into the myocardium, as shown in **FIGURE 12C**. An introducer sheath 96 is advanced over the dilator until the end of the sheath is in the artery lumen. The artery is opened, and the dilator 94 is removed. As shown in **FIGURE 12D**, the conduit 86 is advanced through the introducer sheath, with a pusher or stylet 98 to advance the conduit into the myocardium.

In another embodiment, shown in **FIGURES 13A** and **13B**, coarse threads are used on a device or a tool to hold open the artery. As shown in **FIGURE 13A**, threads 100 which are exemplarily shown are used to penetrate the outer wall of the coronary artery. These threads may be independent as shown, or may be part of a conduit or delivery tool or other member. After the threads penetrate the wall, the threads or the device on which they are attached are pulled back to open the artery. Threading continues as shown in **FIGURE 13B** through the inner wall of the coronary artery.

The embodiments illustrated and described above are provided merely as examples of certain preferred embodiments of the present invention. Other changes and modifications can be made from the embodiments presented

herein by those skilled in the art without departure from the spirit and scope of the invention, as defined by the appended claims.